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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,376	01/31/2007	Christopher Martin Bunce	7492-104	3703

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EXAMINER	
KOSAR, AARON J	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,376	BUNCE, CHRISTOPHER MARTIN	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *9-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/10/06;10/8/08;8/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I and the species hematopoietic, stem or precursor, cells in the reply filed on June 12, 2009 is acknowledged. Since Applicant did not distinctly and specifically point out the supposed errors in the election/restriction requirement, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 are pending of which claims 9-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 12, 2009.

Claims 1-8 have been examined on their merits.

Claim Objections

Claim 1 is objected to because of the following informalities: the term – in – appears to have been inadvertently omitted before the phrase "the presence of".

Appropriate correction is suggested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the instant case the claims are drawn to naturally-occurring processes. As evidenced by Willems et al (Exper. Hematol. 2002, 30, p.640-648.) and Levine (U.S. Patent No. 5,834,217), NM23 is constitutively present in (blood) plasma (Willems, whole document, e.g. abstract) along with hematopoietic progenitor cells. Thus the instant claims remain drawn to *in vivo* conditions and processes and/or processes in naturally-occurring materials (e.g. in blood plasma, cord blood *per se*).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting differentiation, does not reasonably provide enablement for prevention of differentiation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to preventing differentiation; however the specification is drawn to an NM23 protein inhibitory method. Thus, the claims taken together with the specification imply a breadth with is greater than is supported by the disclosure.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art is such that NM23 protein was known as taught by Willems (Exper. Hematol. 2002, 30, p.640-648.), to be inhibitory towards hematopoietic cell differentiation of certain cell lines at the time of the instant invention (e.g. Willems, abstract); however, NM23 was not known to the skilled artisan to be a differentiation preventor.

Applicant have reasonably demonstrated/disclosed that the claimed compound, NM23, in the method is useful as an agent for inhibiting differentiation of certain hematopoietic cells. However, the claims also encompass using the claimed compound to prevent differentiation which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat" or "inhibit", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders/conditions cannot be totally prevented with current therapies/treatments – including preventing hematopoiesis with NM23, which is recognized in the medical art as an inhibitor, but is clearly not recognized in the medical art as being an agent of cell-differentiation prevention.

Since prevention of differentiation with NM23 remains largely unsolved, means for prevention of differentiation as instantly claimed is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high; however, the prevention of differentiation of undifferentiated cells with NM23 remains beyond the purview of the skilled artisan. Thus one would turn to the instant specification for guidance and direction.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided that NM23 may delay or inhibit differentiation (e.g. specification, page 30). However, the specification does not provide sufficient guidance, direction, and is absent working examples of prevention of differentiation.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by Willem and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to prevent differentiation as instantly claimed.

It is the Examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

Claims 2-4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2 and 3, the claims recite the term "cultured cells"; however, it is unclear if the cultures cells of claims 2 and/or 3 are the same or different cells as the cell(s) of claim 1. Clarification is required.

In claims 4 and 7, the claims recite "selected from the group comprising"; however, the claims are unclear and the scope of the claims cannot be unambiguously determined, because the alternative limitations are not recited in a proper Markush group. It is improper to use the term "comprising" instead of "consisting of." Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931). (see MPEP § 2173.05(h)). Clarification is required.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Willems et al (Exper. Hematol. 2002, 30, p.640-648.).

Willems appears to anticipates the claims by teaching NM23 (NM 23 protein), bone marrow cells (cells from bone marrow) and normal human hematopoietic progenitor cells (undifferentiated cells, hematopoietic cells, progenitor or stem cells, cells from blood). Willems further teaches *in vitro* addition of NM23 to the cells, wherein NM23 inhibits cell differentiation (maintains undifferentiated cells).

Although Willems does not expressly recite an intended use of the NM23 as a survival factor or to prevent differentiation/maturation, or of the cultured cells for a (non)therapeutic use Willems still appears to anticipate the claims, because Willems teaches the same cells (hematopoietic cells) and the same protein (NM23) as instantly claimed, and culturing (assaying for differentiation and the inhibition thereof). Thus the method of Willems appears to be

identical to the method as instantly claimed wherein practicing the method of Willems would appear to inherently provide the intended functions/uses.

In the alternative, even if the claimed method of culturing such cells in the presence of NM23 is not identical to the referenced method with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced cells produced by such a method are likely to inherently possess the same characteristics of the claimed cells produced thereby particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed culturing method would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Christopher R. Tate/
Primary Examiner, Art Unit 1655